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Guidance for the Reregistration of Pesticide Products Containing Monocrotophos as the Active Ingredient

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GUIDANCE FOR THE REREGISTRATION OF MANUFACTURING-USE AND CERTAIN END-USE PESTICIDE PRODUCTS

CONTAINING

MONOCROTOPHOS
(058901)

CASE NUMBER 154

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA sec. 3(g)) directs EPA to register all pesticides as expeditiously as possible.

To carry out this task, EPA has established the Registration Standards program, which will review all pesticide products containing active ingredients first registered before January 1, 1977. Pesticides will be reviewed in use clusters which have been ranked to give earliest review to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. EPA's reassessment results in the development of a regulatory position, contained in a Registration Standard, on each pesticide and its uses. The Agency may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses of formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide will not result in adverse effects on the environment.

The scientific review, which is not contained in this Guidance Package but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the end use (formulated) products that contain the active ingredient. If we have serious concerns, we will address end use products as part of the Registration Standards program and will propose regulatory actions to the extent necessary to protect the public.

EPA has the authority under FIFRA sec. 3(c)(2)(B) to require registrants to submit data that will answer our questions regarding the hazard that may result from the intended use of a pesticide. Although sec. 3(c)(2)(B) provides that all registrants are responsible for these data, the Agency generally imposes generic data requirements only on the registrants of the manufacturing use products (basic suppliers of the active ingredient) and other producers who do not qualify for the formulator's exemption.*

A producer who wishes to qualify for the formulator's exemption may change his source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. A registrant may do so by submitting a new Confidential Statement of Formula, EPA Form 8570-4, identifying the registered source of the active ingredient, to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to cancel the registration of any of your products subject to the requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document. If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product which does not comply with the requirements set forth in this Guidance Document.

You are reminded that FIFRA sec. 6(a)(2) requires you to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

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*The formulator's exemption applies to a registrant of a product if the source of his active ingredient(s): (1) is a registered product and (2) is purchased from a source which does not have ownership in common with the registrant's firm.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For the Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

*End use products of registrants who also produce a manufacturing use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing use product(s). Such end use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing use products registered by any company end use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. REGULATORY POSITION AND RATIONALE

A. Introduction

This chapter contains the Agency's regulatory position and rationale on products containing the pesticide monocrotophos as a sole active ingredient. The Agency bases its position and rationale on a consideration of all uses of monocrotophos appearing in pesticide products registered under Sections 3 and 24(c) of the FIFRA as well as in products authorized for distribution in intrastate commerce under 40 CFR 162.17. The Agency has reviewed the known chemical, environmental, and toxicological characteristics of this pesticide and its established tolerances for residues in or on food and feed commodities. From these considerations the Agency sets forth the data and labeling requirements that must be met by registrants and applicants for registration of monocrotophos manufacturing-use (MP) products in order for their products to be registered or reregistered under this Standard. Unique labeling requirements and certain data needs for end-use products (EPs) containing monocrotophos are also established by this Standard.

Only those data and labeling requirements for current and future substantially similar MPs and EPs are addressed here. Applications to register products that differ appreciably from those described in this Standard may be subject to additional data and/or labeling requirements.

B. Description of Chemical

Monocrotophos is the British Standards Institute (BSI) and International Organization for Standardization (ISO) approved common name given to the chemical dimethyl phosphate of 3-hydroxy-N-methyl-cis-crotonamide.

Other names include Apadrin; Azodrin; Bilobran; Crisodrin; Glore Phos 36; Hazodrin; Monocil 40; Monocron; Nuracron; Pillardrin; Plantdrin; Susrin; Ulvair; (E)-phosphoric acid dimethyl [1-methyl-3-(methylamino)-3-oxo-1-propenyl] ester; (E)-phosphoric acid dimethyl ester, ester with 3-hydroxy-N-methylcrotonamide; dimethyl 2-methylcarbamyl-1-methylvinyl phosphate; 3-(dimethoxyphosphinyloxy)-N-methyl-cis-crotonamide; C1414 and SD9129.

Identifying characteristics and codes are as follows:

Empirical Formula:	$C_7H_{14}NO_5P$
Molecular Weight:	223.16
CAS Registry No.:	6923-22-4
ENT Registry No.:	27129
Shaughnessy No.:	058901

Technical monocrotophos is a reddish brown solid with a melting point of 25 to 30 °C. Its odor is characteristic of a mild ester. Monocrotophos is soluble in water, acetone, and alcohol. It is stable when stored in glass or polyethylene containers; stable in simple alcohols and glycols at room temperature; relatively stable in sunlight and nonvolatile at 100 °F; and decomposes at 310 to 320 °F. Monocrotophos hydrolyzes and degrades rapidly in water at 25 °C (half-lives of 14 to 30 days). Its half-life in solution (2 ppm) at pH 7 and 38 °C is 23 days.

The Shell Chemical Company is the sole producer of monocrotophos in the United States and markets its products under the trade name Azodrin®. Their 75 percent technical product is the sole registered monocrotophos manufacturing-use product. There are nine Section 3 registrations, ten 24(c)'s and five intrastate products. These are all single active ingredient products.

Monocrotophos is a contact and systemic insecticide/acaricide registered for use on a variety of field and vegetable crops, and ornamental (nursery stock) sites. Of the total amount of monocrotophos applied in the United States in 1980-82, 38 percent was used on cotton and 25 percent on peanuts. Application rates range from 0.125 to 1.0 lb active ingredient per acre (ai/A). Monocrotophos is only formulated in single active ingredient products. Single active ingredient formulations consist of 3.2 and 5 pounds per gallon soluble concentrate liquid. Monocrotophos is generally foliarly applied using low gallonage ground equipment or low pressure knapsack sprayers, and may be applied using aircraft. Monocrotophos is also applied as a seed treatment on cotton.

Monocrotophos is a restricted-use pesticide. Therefore, applicators must be certified or be under the direct supervision of applicators certified to apply monocrotophos (43 FR 5782, February 9, 1978).

C. Regulatory Position and Rationale

Based on a review and evaluation of all available data and other relevant information on monocrotophos, the Agency has made the following determinations:

1. All products containing monocrotophos as a sole active ingredient may continue to be registered for sale, distribution, reformulation, and use, subject to the terms and conditions specified in this Guidance Document. Registrants must provide, or agree to develop, additional data, as specified in Tables A and B, in order to maintain existing registrations or to permit new registrations.

Rationale: Under FIFRA, the Agency normally does not cancel or withhold registration simply because data are missing or inadequate (see Sections 3(c)(2)(B) and 3(c)(7) of the FIFRA). Rather, issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated after they are received and the Agency will determine at that time whether they will affect the registration(s) of monocrotophos.

2. The Agency will not allow any significant new uses* to be established for monocrotophos until the residue chemistry data deficiencies identified in Table A have been satisfied and a tolerance reassessment has been completed; and a well-designed field study of the effects of monocrotophos on birds has been evaluated.

Rationale: The Agency is unable to complete a tolerance reassessment of monocrotophos because of extensive residue chemistry data gaps. The NOEL for cholinesterase inhibition had resulted in the TMRC for previously published tolerances occupying 397 percent of the ADI (132% based on systemic effects). In order to lower the TMRC, the registrant has voluntarily deleted the use of tomatoes and potatoes from all currently approved products. The registrant has submitted revised product labels to delete use of monocrotophos on tomatoes and potatoes from their Section 3 product labels and canceled their 24(c) and intrastate products which include these uses. These actions together have eliminated the use of monocrotophos on tomatoes and potatoes and therefore lowered the TMRC to 66 percent of the ADI. The data requested in Table A are needed for EPA to reassess the present tolerances, and to determine if monocrotophos concentrates in meat, milk, poultry, or eggs. Additionally, monocrotophos is very toxic to birds and a field study is needed to determine the extent of the hazard to birds (see item 7 below). The Agency will not allow any significant new uses until the field study in birds and the residue data have been received and evaluated.

3. The Agency is requiring applicators with a high exposure to monocrotophos, flaggers for aerial application, mixers, and loaders to wear protective clothing. The use of backpack or knapsack sprayers for application of monocrotophos will be prohibited.

Rationale: The Agency is concerned about possible exposure to applicators handling monocrotophos because of its high acute toxicity. Applicators using aerial application or enclosed ground application equipment will not be required to wear protective clothing because of lower exposure. Backpack sprayers will be prohibited since the applicator exposure is very high and protective clothing requirements may not be followed during warm weather field application, due to excessive heat. Because of high exposure, human flaggers will be prohibited unless they wear protective clothing or unless they are in an enclosed vehicle with a filtered air supply.

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*The terminology "significant new use" is defined in 44 FR 27934, May 11, 1979. In the case of a new food or feed use, the Agency will generally consider as significant an increase in the Theoretical Maximum Residue Concentration of greater than 1 percent.

4. All end-use products containing monocrotophos shall continue to be classified for restricted use.

Rationale: EPA has very limited data on the acute toxicity of end-use products containing monocrotophos. However, based on the high acute oral toxicity of the active ingredient, monocrotophos, the Agency has determined that monocrotophos products should continue to be classified for restricted use.

5. The Agency is requiring that pertinent chemistry and environmental fate data be submitted on an accelerated basis in order to characterize monocrotophos's potential for contaminating ground water.

Rationale: At present, insufficient data are available to fully assess the environmental fate of monocrotophos. Monocrotophos is mobile in soil, and therefore has a potential to contaminate ground water. However, monocrotophos hydrolyzes and degrades rapidly in water (half-lives of 14 to 30 days). Monocrotophos has not been found in ground water. Nevertheless, the Agency has identified a number of chemicals, including monocrotophos, which may have the potential to enter ground water based on factors such as chemical structure, solubility, and use patterns. On June 19, 1984, the Agency issued a Special Data Call-In (DCI) Notice under FIFRA §3(c)(2)(B) requesting that pertinent data be submitted in an expedited manner. The registrant only cited previously existing 1981 studies in response to the 1984 DCI. Four of the seven DCI data requirements; i.e., hydrolysis, photodegradation in water and on soil, and aerobic soil metabolism have been satisfied by current studies. However, anaerobic soil metabolism, mobility and field dissipation studies are still required.

6. The Agency will continue to require the reentry interval of 48 hours, established under 40 CFR 170 for all outdoor uses of monocrotophos in order to minimize exposure to workers entering treated areas, pending the receipt and evaluation of reentry data to assess the potential for exposure to workers coming in contact with crops treated with monocrotophos.

Rationale: The Agency is concerned about possible exposure to workers that come into contact with crops treated with monocrotophos because of its high acute toxicity. For this reason, a Federal reentry interval of 48 hours has already been set for all crops under 40 CFR 170. Because of monocrotophos's high acute toxicity, this reentry interval is being retained. Through this Standard, reentry studies are being required to further evaluate the potential for exposure to monocrotophos. Based on these submitted data, EPA may impose a different reentry interval.

7. The Agency is requiring a well-designed field study of the effects of monocrotophos on birds. The field sites will include a number of sites in each growing area and will investigate monocrotophos exposure to birds from diet and drinking water and the effects on young fledglings using nest boxes. The design of the field testing protocols, selection of sensitive indicator species (including avian predators), and the selection of the test sites must be submitted to the Agency within 120 days from issuance of the Standard. This protocol must be approved by the Agency prior to the initiation of the study. In the interim, precautionary label statements are required.

Rationale: Actual field tests are required by 40 CFR §158.145 if the use of the pesticide is likely to result in adverse effects on wildlife exposed to the pesticide and if such testing can yield data useful in assessing such effects. Monocrotophos is very toxic to birds via acute oral and dietary exposures. Based on laboratory data, significant adverse effects to birds are likely since both expected and measured residue values in the diet and water of avian wildlife approach, are equal to, or are greater than the reported LC_{50} values. Further, substantial avian mortality was observed in many of the incident reports available to the Agency. A number of field studies were submitted to the Agency as well. Although these field studies were generally cursory in nature and inadequately designed, they indicated that significant avian mortality was associated with the use of monocrotophos. These incident reports and deficient field studies are not an adequate basis for regulatory action at this time. However, the laboratory and field reports together raise serious concern that monocrotophos has significant adverse effects on avian wildlife. Therefore, a well designed field test on birds is being required. The additional data being required will permit a more definitive assessment of the nature and extent of the hazard to birds. As an interim regulatory step, the Agency is requiring an environmental hazard label precaution which includes instructions not to use monocrotophos whenever large flocks of birds are in the vicinity.

8. The Agency is requiring all end-use products registered for outdoor use to bear a restriction on rotating food or feed crops to monocrotophos treated soils unless monocrotophos is registered for use on the rotated crop. This restriction will remain in effect until such time as data are submitted and reviewed which allow the Agency to determine a time interval at which rotated crops planted in treated soil will be free of pesticide residues.

Rationale: Rotational crop data requirements have not been satisfied and are required as part of the Generic Data Requirements for monocrotophos. Accordingly, insufficient data are available to determine the potential accumulation of monocrotophos residues in rotated crops. The restriction will ensure that illegal residues or residues of concern do not occur in food or feed crops.

9. The Agency is not requiring additional residue data to determine if any detectable residues of the trimethyl phosphate (TMP) contaminant persist in raw agricultural commodities or processed foods unless the requested plant metabolism study shows that TMP persists.

Rationale: TMP is a minor contaminant in the manufacturing-use product. At high doses (1500 mg/kg and above), TMP tested by itself is a mutagen often used as a positive control substance in mammalian mutagenicity testing, as indicated by positive results in mice for dominant lethals, micronuclei and sperm abnormalities, and in both rat and mouse bone marrow cells for chromosome aberrations.

A 1978 bioassay in mice and rats reported TMP was oncogenic in female (but not male) B6C3F1 mice, inducing adenocarcinomas of the uterine endometrium at high doses (500 mg/kg by gavage 3 times weekly for 103 weeks), with a significant dose-related trend. This tumor type had not previously been observed among 100 historical control females at this laboratory (and was absent in concurrent controls). Additionally, treatment of the rats was associated with the induction of benign fibromas of subcutaneous tissue in male (but not female) Fisher 344 rats at the HDT (100 mg/kg by gavage 3 times weekly for 104 weeks), which also showed a significant dose-related trend.

The Agency dose not consider that monocrotophos, even in the presence of minor amounts of this TMP contaminant, constitutes a dietary carcinogenic hazard in its registered uses, because of the following:

1. TMP represents only a minor contaminant of the manufacturing-use product (not more than 1 percent), and thus any contaminated residues from the use of end-use formulations would be at fractions of this level. This potential contamination of TMP would represent a very small amount of intake with a maximum TMRC of 0.3 microgram/day or 0.005 microgram/kg/day (60kg body weight for humans) based upon published tolerances for monocrotophos.

2. Two-year feeding studies in rats and mice at levels up to 10 ppm monocrotophos with a potentially maximum amount of TMP of 0.1 ppm in the diet (5 microgram/kg/day) revealed no evidence of carcinogenicity. Thus, the amounts of TMP tested in the oncogenicity studies of monocrotophos are approximately 1000-fold higher than the potential exposure from foods (0.005 microgram/kg/day).

3. A carcinogenic risk assessment for the TMP contaminant in monocrotophos estimated the risk from dietary exposure at 10^{-8} to 10^{-9}. This risk assessment assumed the maximal contamination of TMP in monocrotophos (1%) and that none of the TMP had degraded.

However, the Agency is requiring data on the persistence of TMP in the plant metabolism study. Additional TMP residue data will be required if the plant metabolism study shows that TMP persists.

The Agency has also evaluated the risk to applicators of monocrotophos from the TMP contaminant. Exposure to TMP may occur to applicators by mixer/loader and sprayer exposures for tobacco, cotton and peanut crops. The exposure of applicators to TMP was lower from the tobacco and peanut crops than from cotton. The carcinogenic risk of TMP for cotton applicators is estimated over 35 years to be 10^{-6} to 10^{-7}. In view of lower exposure to TMP from tobacco and peanut crops, the carcinogenic risk would be lower for these applicators.

Also, because of the high acute toxicity of monocrotophos (the NOEL for cholinesterase inhibition has been set at 0.03 ppm), this Standard is imposing labeling requirements that applicators wear protective clothing and an approved respirator to lower applicator exposure. Accordingly, the Agency does not consider that the TMP contaminant constitutes a carcinogenic hazard to applicators of monocrotophos.

10. Registrants of manufacturing-use and end-use products must submit revised labeling which incorporates the label precautions found in Section F.

Rationale: The Agency believes that label statements prescribed in this Guidance Document should minimize the acute hazards associated with the oral, dermal, inhalation, and ocular routes of exposure to users of monocrotophos, and should minimize the hazards to terrestrial and aquatic organisms from use of these products.

D. Criteria for Registration Under This Standard

To conform to this Standard, products must contain monocrotophos as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use-pattern requirements listed in Section E of this document. The application for registration or reregistration of manufacturing-use products subject to this Standard must comply with all terms and conditions described in it, including submission of an up-to-date Confidential Statement of Formula, submission of revised labeling, commitment to fill data gaps on the schedule specified by the Agency and, when applicable, offer to pay compensation as required by 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D) and 136(c)(2)(D). Registrants of end-use products who qualify for the Formulator's Exemption must submit five (5) copies of draft labeling incorporating the unique label statements identified in Section F.

E. Acceptable Ranges and Limits

Product Composition Standard

To conform to this Standard, manufacturing-use products (MP) must contain monocrotophos as the sole active ingredient. Each MP formulation proposed for registration must be fully described with the appropriate certification of limits, stating maximum and minimum amounts of the active and intentionally added inert ingredients which will be present in products.

Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing monocrotophos in all toxicity categories, provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

Use Patterns

To conform to this Standard, manufacturing-use products containing monocrotophos may be labeled for formulation into end-use products only for the commodities listed below. The attached index entry lists all registered uses (and intrastate label uses*) as well as approved maximum application rates and frequencies.

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*Product uses that appear only on the labels of intrastate products have not been subject to review under Sec. 3 of the FIFRA. Therefore, these uses may not be added to any product registered under Sec. 3 until the supporting data have been submitted, reviewed, and found to be acceptable.

- Terrestrial, nondomestic, food uses on: cotton, peanuts, and sugarcane.

- Terrestrial, nondomestic nonfood uses on: tobacco, ornamental conifers (nursery stock), ornamental flowering plants (nursery stock), ornamental woody shrubs (nursery stock), and ornamental deciduous trees (nursey stock).

F. Required Labeling

All manufacturing-use and end-use monocrotophos products must bear appropriate labeling as specified in 40 CFR 162.10. The guidance package for this Standard contains information on label requirements. All labeling changes must appear on all products released for shipment by September, 1986. All labeling changes must appear on all products in channels of trade by September, 1987.

- Ingredient Statement

  The ingredient statement for MPs and EPs must list the active ingredient as:

  dimethyl phosphate of 3-hydroxy-N-methyl-cis-crotonamide

- Use Pattern Statement

  All manufacturing-use monocrotophos products must state that they are intended for formulation into end-use products for the aforementioned use patterns. Labeling must specify sites, which are listed in Use Patterns, Section 5.3. No use (including intrastate uses) may be included on the label where the registrant fails to agree to comply with the data requirements in either Table A or Table B for that use pattern.

- Precautionary Statements

Statements for Manufacturing-Use Products

1. Labels for manufacturing-use monocrotophos must bear statements reflecting the compound's acute human toxicity. Monocrotophos is in Toxicity Category I by the oral route of exposure; required precautionary statements associated with this category are specified in 40 CFR 162.10.

2. The following revised environmental hazard statement must appear on all MP labels:

   This pesticide is extremely toxic to wildlife and toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Statements for End-Use Products

1. All end-use products must bear the restricted use statement:

   RESTRICTED USE PESTICIDE

   Because of acute human oral toxicity and hazards to birds.

   For retail sale to and use only by Certified Applicators or persons under their direct supervision, and only for those uses covered by the Certified Applicator's Certification.

2. The worker protection statements below apply to all application methods except aerial application and ground application using an enclosed tractor cab or cockpit with a filtered air supply:

   During mixing/loading or ground application wear a protective suit which affords entire body protection except for the feet, hands and head. Wear gloves impermeable to (Product Trade Name•); a hat, boots, goggles, and a pesticide respirator jointly approved by the Mining Enforcement and Safety Administration and the National Institute for Occupational Safety and Health. When handling the concentrated products, wear a face shield and chemical resistant apron. Wash thoroughly with soap and water after handling and before eating, urinating, or smoking. Remove and wash clothing before reuse. Clothing should be laundered separately from household articles.

Replace gloves after each use. Clothing which has been drenched or heavily contaminated and used gloves should be disposed of in accordance with state or local regulations.

3. The reentry statement below must appear on all monocrotophos products that have directions for outdoor use:

   Do not reenter treated fields within 48 hours unless appropriate protective clothing, as specified on this label for ground applicators, is worn.

   (The protective clothing and respirator must be specified if not specified elsewhere on the label.)

4. In the absence of crop rotation data, the crop rotation restriction below must be placed on all EP's:

   Do not plant any food or feed crop in monocrotophos treated areas other than those with registered monocrotophos uses.

5. The environmental hazard statement below must appear on all monocrotophos end-use products:

   This pesticide is extremely toxic to wildlife and toxic to aquatic invertebrates. Wildlife in treated areas may be killed. Do not use whenever large flocks of birds are in the vicinity or when they are observed feeding in or around fields to be treated. Drift and runoff from treated areas will be hazardous to wildlife and aquatic organisms in neighboring areas. Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes.

6. The use statement below must appear on all monocrotophos end-use products:

   The use of backpack or knapsack sprayers for application of this pesticide is prohibited.

7. The following label statement must appear on all products intended for aerial application:

   Automatic flagging devices should be used whenever feasible.

If human flaggers are employed they must wear the appropriate protective clothing and respirator; as specified on this label for ground applicators; or be in an enclosed vehicle with a filtered air supply.

(The protective clothing must be specified as listed in item 2 above, if not specified elsewhere on the label.)

G. Tolerance Reassessment Summary

The established tolerances for monocrotophos are published in 40 CFR 180.296 and 21 CFR 193.151. A summary of these tolerances is presented in Table I.

It should be noted that data gaps exist for metabolism of monocrotophos in plants and animals, and for the storage stability of monocrotophos in plants. Because the requested residue data and perhaps the continued adequacy of all established tolerances are dependent upon the results of the above studies, the metabolism and stability data must be collected prior to the required residue data. The conclusions stated below are subject to change on receipt of the required metabolism and storage stability data.

Sufficient data are available to ascertain that the established tolerances for residues of monocrotophos in or on the following raw agricultural commodities are sufficient to cover anticipated residues: potatoes, tomatoes, cottonseed, peanut hulls, and sugarcane (40 CFR 180.296 and 21 CFR 123.151). However, additional data are required to support the tolerance for residues in or on peanuts (40 CFR 180.296). Furthermore, additional data must be submitted to determine whether food/feed additive tolerances must be proposed for the processed products of potatoes, cottonseed, peanuts, sugarcane, and tomatoes. Feeding and grazing restrictions or a tolerance proposal is needed for the raw agricultural commodity, sugarcane forage.

Registrations exist for several commodities for which no tolerances have been established. A California 24(c) label (CA 82003100) permits use of monocrotophos on Bermuda grass grown for seed; no grazing or feeding restrictions on this use exist. Residue data and an appropriate tolerance proposal covering this use must be submitted to support the continued registration of this product. A California intrastate label (201-5710) permits use of monocrotophos on nonbearing citrus and a California 24(c) label (CA 83002800) permits use on deciduous fruit and nut trees (field-grown 1-year old nursery stock). Data must be submitted to determine whether these uses may be considered nonfood uses; if they are considered food uses, residue data and a tolerance proposal covering these uses must be submitted to support the registration of these products.

The primary toxicological concern associated with monocrotophos is cholinesterase (ChE) inhibition. Previously, the Agency had based the ADI upon a 1967 chronic dog study, providing a No-Observed-Effect Level (NOEL) of 1.6 ppm (0.04 mg/kg/day) for ChE inhibition and a safety factor of 10. The resulting ADI was estimated to be 0.004 mg/kg/day supporting a Maximum Permissable Intake (MPI) of 0.2400 mg/kg for a 60 kg person. These estimates resulted in a Theoretical Maximum Residue Contribution (TMRC) occupying only 15 percent of the ADI for published tolerances.

However, more recent submissions in support of additional tolerances on corn (which have since been denied due to data deficiencies) indicate that toxic effects to monocrotophos in the chronic rat feeding study provide a more sensitive indicator for determining an ADI. In that study, the NOEL for cholinesterase inhibition (ChE) has been set at 0.03 ppm (and for systemic effects at 0.9 ppm), generating an ADI of 0.00015 mg/kg/day (systemically, 0.00045 mg/kg/ day), which results in the TMRC for previously published tolerances occupying 397 percent of the ADI (132% based on systemic effects). Thus, on either basis (ChE or systemic), the margins of safety have been exceeded for those tolerances already published which precludes granting any new requests.

The Agency has set the NOEL for cholinesterase inhibition at the 0.03 ppm level based on a two-year chronic rat feeding study which showed minor depressive trends in ChE at 0.09 ppm. This position is supported by the 8- and 13-week rat feeding study which indicated minor but consistently depressed cholinesterase inhibition in blood and brain at 0.1 ppm.

The Agency was concerned about the fact that the TMRC was 397 percent of the ADI. Since the ADI is based on ChE inhibition which may occur during acute poisoning there is a possibility that a localized population consuming a large quantity of monocrotophos-treated products could be at risk. This problem is most severe and likely to occur with tomatoes since it is a commodity which, after treatment with monocrotophos, could be ingested in large quantities by localized populations as a fresh uncooked product. Although less than 1 percent of the tomatoes in the U.S. are treated with monocrotophos, nearly all the tomatoes treated are for fresh market consumption. Even though less than 1 percent of the monocrotophos sold is used on tomatoes, the food factor for tomatoes is high compared to the other crops which make up the TMRC for monocrotophos (i.e., cottonseed, peanuts, potatoes, and sugar), resulting in tomatoes alone accounting for 60 percent of the TMRC.

In order to lower the TMRC, the registrant has voluntarily deleted the use of tomatoes and potatoes from all currently approved products. Specific residue chemistry and toxicology data requirements for tomatoes and potatoes remain in the Registration Standard to preclude approval of any requests for label modification to include these crops without the required data. Additionally, if these data requirements are not fulfilled, U. S. tolerances on these crops will be considered for tolerance revocation. The elimination of the use of monocrotophos on tomatoes and potatoes has lowered the TMRC to 66 percent of the ADI. Nevertheless, the Agency will not allow any new uses to be established for monocrotophos until the required residue chemistry data (including animal metabolism studies) and the bird field study have been submitted and evaluated so that a tolerance reassessment and bird hazard assessment can be made.

TABLE I

SUMMARY OF PRESENT MONOCROTOPHOS TOLERANCES (ppm)

Commodity	United States[a]	Canada[a]	Mexico	International (codex)
Potatoes[6/]	0.1		0.1	.05
Tomatoes[6/]	0.5	0.5	0.5	1.0
Cottonseed	0.1		0.1	0.1
Peanuts	.05		.05	
Sugarcane	0.1		0.1	
Concentrated tomato products	2.0			

[a/] per se

[6/] In order to lower the TMRC, the registrant has voluntarily deleted the use of tomatoes and potatoes from all currently approved products. Specific residue chemistry and toxicology data requirements for tomatoes and potatoes remain in the Registration Standard to preclude approval of any requests for label modification to include these crops without the required data. Additionally, if these data requirements are not fulfilled, U. S. tolerances for these crops will be considered for revocation.

DIMETHYL PHOSPHATE OF 3-HYDROXY-N-METHYL-CIS-CROTONAMIDE*

TYPE PESTICIDE: Insecticide, Acaricide

FORMULATIONS:
Tech (75%)
SC/L (3.2 lb/gal, 5 lb/gal)

GENERAL WARNINGS AND LIMITATIONS: RESTRICTED USE PESTICIDE. Do not enter treated areas for 48 hours unless appropriate protective clothing is worn. During mixing/loading or application wear a protective suit which affords entire body protection except for the feet, hands and head. Wear gloves impermeable to monocrotophos; a hat, boots, goggles, and a pesticide respirator jointly approved by the Mining Enforcement and Safety Administration and the National Institute for Occupational Safety and Health. A helmet with visor may be substituted for the hat and goggles during aerial application. When handling the concentrated products, wear a face shield and chemical resistant apron. This pesticide is extremely toxic to wildlife and toxic to aquatic invertebrates. Wildlife in treated areas may be killed. Do not use whenever large flocks of birds are in the vicinity or when they are observed feeding in or around fields to be treated. Drift and runoff from treated areas will be hazardous to wildlife and aquatic organisms in neighboring areas. Do not spray border areas. Keep border areas within 25 feet of field free of bird feed and shelter. For additional restrictions for the San Joaquin Valley of CA see cotton. Do not apply as a ultra low volume spray. May be applied by low gallonage ground equipment. The use of backpack or knapsack sprayers for application of this pesticide is prohibited.

Bee Caution:
Monocrotophos is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply monocrotophos or allow it to drift to blooming crops or weeds if bees are visiting the area.

Agricultural Crop Tolerances

Concentrated tomato products	2.0 ppm
Potato	0.1 ppm
Tomato	0.5 ppm

*monocrotophos
Azodrin
3-(dimethoxyphosphinyloxy)-N-methyl-cis-crotonamide

DIMETHYL PHOSPHATE OF 3-HYDROXY-N-METHYL-CIS-CROTONAMIDE

TERRESTRIAL FOOD CROP

(Agricultural Crops)

General Warnings and Limitations: Do not plant any food or feed crop in monocrotophos treated soils other than those with registered monocrotophos uses. Unless otherwise specified apply in sufficient water for thorough coverage.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/28007AA	Cotton		0.1 ppm (cottonseed) 21 day preharvest interval through 1 pound per acre for foliar application. Seed treatment through 25 pounds per ton of delinted cottonseed. Do not graze livestock on treated fields or use treated trash for feed. Do not apply more frequently than 5 to 7 day intervals. For foliar applications in the San Joaquin Valley CA, do not apply later than 14 days after initiation of bloom and not after July 15 to prevent injury to wildlife. May be applied by aircraft.
ITBCCNA	Beet armyworm	0.4-0.8 lb/A (3.2-5 lb/gal SC/L)	Foliar application.
INASAHA ITAMAOA	Boll weevil Pink bollworm	0.6-1 lb/A (3.2-5 lb/gal SC/L)	Foliar application.
ITBCBOA ITAAAOA ILAAABA	Bollworm Loopers Mites	0.5 lb/A (3.2-5 lb/gal SC/L)	Foliar application. Apply for light infestations.
		0.5-1 lb/A (3.2-5 lb/gal SC/L)	Foliar application. Apply for heavy infestations.
IQAMARA	Lygus bugs	0.5 lb/A (3.2 lb/gal SC/L) or 0.55 lb/A (5 lb/gal SC/L)	Foliar application. Apply for early season infestations.

DIMETHYL PHOSPHATE OF 3-HYDROXY-N-METHYL-CIS-CROTONAMIDE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Cotton (continued)		
		0.5-1 lb/A (3.2-5 lb/gal SC/L)	Foliar application. Apply for late season or heavy infestations.
IMOAAAA	Thrips	0.125-0.2 lb/A (3.2-5 lb/gal SC/L)	Foliar application.
		5-25 lb/ton of delinted seed (5 lb/gal SC/L)	Seed treatment. Apply for uniform coverage using a commercial seed treater. Labeling claims control through first squaring. Do not plant treated seed when soil temperature is below 65 F (18.3 C) or when early season growing conditions are expected to be adverse. Treatment may reduce germination however plant at same rate as untreated seed. Do not store treated seed in proximity of feed or food. May be mixed with 5-ethoxy-3-(trichloromethyl)-1,2,4-thiadiazole and chloroneb.
IRABAAA	Whiteflies	0.23-1 lb/A (3.2-5 lb/gal SC/L)	Foliar application.
/28015AA	Peanuts		0.05 ppm (peanuts) 0.5 ppm (peanut hulls) 15 day preharvest interval through 1 pound per acre for band and foliar applications. Do not make more than 2 applications during the growing season. Do not feed treated vines or hay to livestock. Do not graze livestock on treated fields. May be applied by aircraft.
ITBCBLA	Granulate cutworm	1 lb/A (3.2-5 lb/gal SC/L)	Foliar application.
ITBMBOA	Lesser cornstalk borer	1 lb/A (3.2-5 lb/gal SC/L)	Band application. Apply a 10 to 12 inch band to the soil surface and to the lowest stems and foliage.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Peanuts (continued)		
LAAABA	Mites	0.5-1 lb/A (3.2-5 lb/gal SC/L)	Use limited to the southeastern states. Foliar application. Apply the lower dosage for light infestations and the higher dosage for heavy infestations.
		0.75-1 lb/A (3.2-5 lb/gal SC/L)	Use limited to the southwestern states. Foliar application. Apply the lower dosage for light infestations and the higher dosage for heavy infestations.
25003AA	**Sugarcane**		0.1 ppm 30 day preharvest interval through 0.75 pound per acre for foliar application by aircraft. Aerial application should be made as close to the cane top level as possible. Apply in a minimum of 2 gallons of water per acre. Apply by aircraft only.
RACAAA LAAABA	Aphids Mites	0.75 lb/A (5 lb/gal SC/L)	Use limited to FL. Foliar application.
TAMBAA	Sugarcane borer	0.75 lb/A (5 lb/gal SC/L)	Use limited to the Continental United States. Foliar application.
	TERRESTRIAL NON-FOOD CROP		
	(Agricultural Crops)		
26003AA	**Tobacco (excluding shade-grown)**		N.F. 5 day preharvest interval through 1 pound per acre for foliar application. May be applied by aircraft.
IRACCUA ITBRAKA	Green peach aphid Tobacco hornworm	0.5 lb/A (3.2 lb/gal SC/L) or	Foliar application.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Tobacco (excluding shade-grown) (continued)		
		0.55 lb/A (5 lb/gal SC/L)	
ITBCBNA	Tobacco budworm	0.5-1 lb/A (3.2-5 lb/gal SC/L)	Foliar application. Apply the lower dosage for light infestations and the higher dosage for heavy infestations.

(Ornamental Plants and Forest Trees)

General Warnings and Limitations: Do not transplant, pick or otherwise handle the treated ornamentals until 2 days after application. Apply in up to 100 gallons of water per acre. Apply to the point of run-off. Unless otherwise noted, repeat at 14 day intervals as needed.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/35007DA	Ornamental Conifers (nursery stock)		
ILAAABA	Mites	0.6 lb/A (3.2 lb/gal SC/L) or 0.63 lb/A (5 lb/gal SC/L)	Foliar application to nursery stock. A second application 14 days later may be needed.
ISAAABA	Sawflies	0.3 lb/A (3.2 lb/gal SC/L) or 0.313 lb/A (5 lb/gal SC/L)	Foliar application to nursery stock.
/35044DA	(Douglas Fir (nursery stock))		
/35098DA	(Pine (nursery stock))		
/35116DA	(Spruce (nursery stock))		
IRACAAA	Aphids (including green peach aphid)	0.6 lb/A (3.2 lb/gal SC/L) or 0.63 lb/A (5 lb/gal SC/L)	Foliar application to nursery stock.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/35006DA	Ornamental Deciduous Trees (nursery stock)		
IRACAAA	Aphids (including green peach aphid)	0.6 lb/A (3.2 lb/gal SC/L) or 0.63 lb/A (5 lb/gal SC/L)	Foliar application to nursery stock. Apply when nymphs appear.
IRAFAAA ILAAABA	Leafhoppers Mites	0.6 lb/A (3.2 lb/gal SC/L) or 0.63 lb/A (5 lb/gal SC/L)	Foliar application to nursery stock. A second application 14 days later may be needed.
ISAAABA	Sawflies	0.3 lb/A (3.2 lb/gal SC/L) or 0.313 lb/A (5 lb/gal SC/L)	Foliar application to nursery stock.
/35028DA	(Birch (nursery stock))		
IMAAAGA	Leafminers	0.3 lb/A (3.2 lb/gal SC/L) or 0.313 lb/A (5 lb/gal SC/L)	Foliar application to nursery stock.
/31003DA	Ornamental Flowering Plants (nursery stock)		
IRACAAA	Aphids (including green peach aphid)	0.6 lb/A (3.2 lb/gal SC/L) or 0.63 lb/A (5 lb/gal SC/L)	Foliar application to nursery stock. Apply when nymphs appear.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Ornamental Flowering Plants (nursery stock) (continued)		
ITBCCSA	Cabbage looper	0.6 lb/A (3.2 lb/gal SC/L) or 0.63 lb/A (5 lb/gal SC/L)	Foliar application to nursery stock. Apply when larvae begin feeding. A second application 14 days later may be needed.
IRAFAAA ILAAABA	Leafhoppers Mites	0.6 lb/A (3.2 lb/gal SC/L) or 0.63 lb/A (5 lb/gal SC/L)	Foliar application to nursery stock. A second application 14 days later may be needed.
IMOAAAA	Thrips (including Cuban laurel thrips)	0.6 lb/A (3.2 lb/gal SC/L) or 0.63 lb/A (5 lb/gal SC/L)	Foliar application to nursery stock. Repeat at 14 day intervals or as needed.
/31108DA	(Geraniums (nursery stock))		
ITBCBNA	Tobacco budworm	1 lb/A (3.2 lb/gal SC/L) or 0.94 lb/A (5 lb/gal SC/L)	Foliar application to nursery stock. Up to 3 applications at 30 day intervals may be needed.
/34004DA	Ornamental Woody Shrubs (nursery stock)		
IQAMAAA	Plant bugs	0.47 lb/A (5 lb/gal SC/L)	Foliar application to nursery stock.
IMOAAAA	Thrips (including Cuban laurel thrips)	0.4 lb/A (3.2 lb/gal SC/L) or 0.47 lb/A (5 lb/gal SC/L)	Foliar application to nursery stock. Repeat at 14 day intervals or as needed.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Ornamental Woody Shrubs (nursery stock) (continued)		
34002DA 34120DA MAAAGA	(Azalea (nursery stock)) (Rose (nursery stock)) Leafminers	0.3 lb/A (3.2 lb/gal SC/L) or 0.313 lb/A (5 lb/gal SC/L)	Foliar application to nursery stock. Apply when leaves are expanded and small mines begin to appear.

AERIAL, MOTHPROOFING AND TANK MIX APPLICATIONS

001500 AAAAAA	Aerial Application		
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Cotton, Peanuts, Sugarcane TERRESTRIAL NON-FOOD CROP (Agricultural Crops) Tobacco	
900300 AAAAAA	Tank Mix		
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Cotton	

EPA Compendium of Acceptable Uses

DIMETHYL PHOSPHATE OF 3-HYDROXY-N-METHYL-CIS-CROTONAMIDE

Listing of Registered Pesticide Products by Formulation

6075.0001 75% technical chemical
dimethyl phosphate of 3-hydroxy-N-methyl-cis-crotonamide (058901)
000201-00219

6103.2015 3.2 lb/gal soluble concentrate/liquid
dimethyl phosphate of 3-hydroxy-N-methyl-cis-crotonamide (058901)
000201-00264 000201-00268 000201-00278 000201-00343

6105.0015 5 lb/gal soluble concentrate/liquid
dimethyl phosphate of 3-hydroxy-N-methyl-cis-crotonamide (058901)
000201-00157 000201-00342 002749-00178 010417-00001

9999999 State Label Registrations

AZ Reg. No.
000201-05708 010163-06120

CA Reg. No.
000201-05709 000201-05710 010951-09813

1

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Timeframe Listed Below 1/
§158.120 Product Chemistry						
Product Identity:						
61-2 - Product Identity and Disclosure of Ingredients	TGAI	R	☒	☐		6 Months
61-3 - Discussion of Formation of Impurities	TGAI	R	☒	☐		6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	CR	☒	☐		12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	R	☒	☐		6 Months
63-3 - Physical State	TGAI	R	☒	☐		6 Months
63-4 - Odor	TGAI	R	☒	☐		6 Months
63-5 - Melting Point	TGAI	R	☒	☐		6 Months
63-6 - Boiling Point	TGAI	R	☐	☒	2	6 Months

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TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required		Footnote Number	Data must Be Submitted Within Timeframe Listed Below 1/
			Yes	No		
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	☒	☐	______	6 Months
63-8 - Solubility	TGAI or PAI	R	☒	☐	______	6 Months
63-9 - Vapor Pressure	PAI	R	☒	☐	______	6 Months
63-10 - Dissociation constant	PAI	R	☒	☐	______	6 Months
63-11 - Octanol/water partition coefficient	PAI	R	☒	☐	______	6 Months
63-12 - pH	TGAI	R	☒	☐	______	6 Months
63-13 - Stability	TGAI	R	☒	☐	______	6 Months
Other Requirements:						
64-1 - Submittal of samples	TGAI, PAI	CR	☐	☒	______	

: :

TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient; R = Required; CR = Conditionally Required

1/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
- 6 Month Due Date is March, 1986.
- 12 Month Due Date is September, 1986.

2/ Not required because the 75% technical is a solid at room temperature.

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Data Requirements	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe For Data Submission 2/
§158.125 Residue Chemistry				
171-2 - Chemical Identity	TGAI	No	-	Yes4/ 6 Months
171-3 - Directions for Use	--	No	-	Yes5/ 6 Months
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partially	00013501 00109093 00013506 00013504 GS0154016	Yes6/ 18 Months
- Livestock	PAIRA and Plant Metabolites	Partially	00028574 00109093 GS0154017	Yes7/ 18 Months
171-4 - Residue Analytical Method				
- Plant residues	TGAI and Metabolites	Yes	00013516, 00013967 00013969, 00013999 00028574, 00033357 00040240, 00040243 00040245, 00040246 00040247, 00040248 00040655, 00090961 00099011, 00102435 00102446, 00102448 00102453, 00102472 00102473, 0019093 05002358, GS0154018 GS0154019, GS0154020 GS0154021	No8/

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Data Requirements	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe For Data Submission [2]
§158.125 Residue Chemistry - Continued				
- Animal residues	TGAI and Metabolites	No	-	No[9]
171-4 - Storage Stability Data	PAI	Partially	00056941 00102446 00109093	Yes[10] 24 Months
171-4 - Magnitude of the Residue - Residue Studies for Each Food Use[11]				
- Root and tuber vegetables[12]				
° Potatoes	TEP	Partially	00102446 00102458	Yes[13]
° Potatoes (processed)	EP	No	-	No[14]
- Fruiting vegetables (Except cucurbits)[15]				
° Tomatoes	TEP	Yes	00102472	No
° Tomatoes (processed)	EP	Partially	00102472	No[16]
- Miscellaneous Commodities				
° Cottonseed	EP	Partially	00099011 00102435	Yes[17]/24 Months
° Peanuts	EP	Partially	00040240 00040248	Yes[18]/24 Months
° Sugarcane	EP	Partially	00102446 00102464	Yes[19]/24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 2/
§158.125 Residue Chemistry - Continued				
171-4 - Magnitude of the Residue - Residue Studies (continued)				
- SLN or 24(c) Uses Swiss Chard, Corn (seed) deciduous fruit and nut trees, Bermuda grass grown for seed	TEP	No	-	Yes 24 Months
- Intrastate Uses Nonbearing Citrus	TEP	No	-	Yes 24 Months
— Meat/Milk/Poultry/Eggs	TGAI or Plant Metabolites	No	-	Reserved20/
- Potable Water	EP	Not Applicable		
- Fish	EP	Not Applicable		
- Irrigated Crops	EP	Not Applicable		
- Food Handling	EP	Not Applicable		
171-5 - Reduction of Residue	Residue of Concern	No		Yes21/ 9 Months
171-6 - Proposed Tolerance 3/	Residue of Concern	No		Yes22/24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Data Requirement	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission[2/]
§158.125 Residue Chemistry - Continued				
171-7 - Reasonable Grounds in Support of Petition	--	No		Yes[23/] 6 Months
171-11 - Tobacco	EP	No	-	Yes[24/]24 Months
171-13 - Submittal of Analytical Reference Standards	PAIRA	Reserved[25/]		

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

§158.125 Residue Chemistry - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product; EP = End-use product.

2/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.

- 6 Month Due Date is March, 1986.
- 9 Month Due Date is June, 1986.
- 18 Month Due Date is March, 1987.
- 24 Month Due Date is September, 1987.

3/ Includes filing fee.

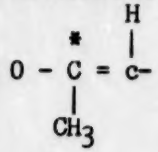
4/ The same chemical identity data as required under §158.120 are required, with emphasis on impurities that would constitute a residue problem.

5/ Required information includes crops to be treated, rate of application, number and timing of applications, preharvest intervals and relevant restrictions.

6/ The following additional data are required:

- Residues of [^{32}P] or [^{14}C] monocrotophos must be characterized and quantified in or on cottonseed produced from seed treated with 25 lb ai/ton of delinted seed. Exaggerated rates may be necessary to obtain sufficient activity for identification.
- Residues of [^{32}P] or [^{14}C] monocrotophos must be characterized and quantified in or on peanuts grown in soil treated twice at 1 lb ai/A; peanuts must be harvested 15 days after the final application. Exaggerated rates may be necessary to obtain sufficient activity for characterization. The residue data must also include residues of the trimethyl phosphate contaminant.
- In addition the residue data should show evidence regarding the fate and stability of trimethyl phosphate (TMP) in plants.
- Crop field trials should not be started until the plant metabolism study has been completed.

NOTE: Labeling should take place at carbon atom with asterisk



$$O-\underset{CH_3}{\overset{*}{C}}=\overset{H}{C}-$$

7/ The following additional data are required:

- Metabolism studies utilizing ruminants. Animals must be dosed for 3 days with either [^{32}P] or [^{14}C] monocrotophos at a concentration in the total diet which will result in sufficient residues in the milk, liver, muscle and fat for characterization. Animals must be sacrificed within 24 hours of the final dose (milk must be collected twice daily).

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

§158.125 Residue Chemistry - Continued

- Metabolism studies utilizing poultry. Animals must be dosed for 3 days with either [^{32}P] or [^{14}C] monocrotophos at a concentration in the total diet which will result in sufficient residues in the eggs, liver, kidney, fat, and muscle for characterization. Eggs must be sampled twice daily throughout the treatment period. Animals must be sacrificed within 24 hours of the final dose. If poultry metabolism is found to differ significantly from that of ruminants, then nonruminant (swine) data will be required (i.e., in the absence of rat metabolism data.) If poultry and ruminant metabolism differ from that in the rat then additional swine data are required. (Note: The type of labeling should be the same for both animal and plant metabolism studies.)

8/ The nature of the residue in plants and the nature of the residue in animals are not adequately understood. On receipt of the data requested in the plant and animal metabolism sections the adequacy of the analytical methods listed here may be subject to reevaluation; this could result in the requirement of development and submission of additional methods for data collection and tolerance enforcement.

9/ Although no tolerances for residues in animal products presently exist, this requirement is reserved pending the completion of the required plant and animal metabolism studies.

10/ Since most of the residue data submitted provide no information as to storage interval or conditions prior to analysis, the following information is required:

- Details must be provided as to the conditions and length of storage of samples of peanuts, peanut hulls, and sugarcane from which data were generated in support of established tolerances. If any storage interval was >8 months, stability data reflecting that storage interval must be submitted, and residue data submitted in support of the tolerance in question must be corrected for degradation of residues in storage; this may result in reevaluation of established tolerances. This same requirement would apply to any future applications to reinstate the tomato and/or potato use.

It is recommended that samples from which any data required in this Standard are generated be stored frozen for no more than 8 months prior to analysis.
The nature of the residue in plants is not adequately understood. If the requested data indicate additional residues of toxicological concern, data reflecting the stability of such residues in frozen storage may be required.

11/ Data are required on whether actual measurable residues of trimethyl phosphate (TMP) result in or on raw agricultural commodities and processed foods/feed from the maximum registered use of monocrotophos.

12/ A crop group tolerance is not appropriate at the present time for the following reasons:

- Residue data are required for three additional representative members of this group (carrot, radish, and sugar beet); currently, a tolerance exists for residues in or on potatoes only.

13/ Any future application to reinstate the potato use must include residue data to provide a basis for examining the possibility of lowering the tolerance on potatoes to a level equal to or lower than the .05 ppm International (Codex) tolerance.

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

§158.125 Residue Chemistry - Continued

14/ Additional data are needed to determine whether food additive tolerances are needed for processed products of potato. Therefore, the following additional data are required to support any future application to reinstate the potato use:

- Residues of monocrotophos must be determined in dried potatoes, potato granules, and potato chips processed from potatoes bearing measurable weathered residues. It may be necessary to treat at exaggerated rates to obtain measurable residues in the raw agricultural commodity. If concentration of residues occurs in any of these processed commodities, appropriate food additive tolerances must be proposed.

15/ A crop group tolerance is not appropriate at the present time for the following reasons:

- Residue data are required for an additional representative member (peppers) of this crop group; currently, a tolerance exists for residues in or on tomatoes only.

16/ Any future application to reinstate the tomato use must include residue data reflecting the maximum proposed use and to determine if a feed additive tolerance is needed for wet and dry pomace. Residue data in tomato puree, catsup, dry pomace would also be required.

17/ Inadequate processing studies were submitted. Therefore the following additional data are required:

- Residues of monocrotophos must be determined in meal, hulls, soapstock, crude oil, and refined oil processed from cottonseed bearing measurable weathered residues. It may be necessary to apply exaggerated rates to obtain detectable residues in the raw agricultural commodity. If residues concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.

18/ A decision as to the adequacy of the established tolerance for residues in or on peanuts must be postponed pending receipt of the data requested below regarding analytical methods used to generate residue values. In addition, an inadequate processing study was submitted. Therefore, the following additional data are required:

- A description of the analytical method(s) used to generate the data contained in the following reports must be submitted: TIR-24-124-70, TIR-24-143-70, TIR-24-166-70, TIR-24-168-70, TIR-24-100-71 (MRID 00040248).

- Data for residues in meal, crude oil, refined oil, and soapstock processed from peanuts bearing measurable weathered residues. It may be necessary to apply exaggerated rates to obtain detectable residues in the raw agricultural commodity. If residues concentrate in any of these processed products, appropriate food/feed tolerances must be proposed.

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

§158.125 Residue Chemistry - Continued

19/ Inadequate sugarcane processing studies were submitted. In addition, because sugarcane forage is a raw agricultural commodity used for animal feed, a tolerance proposal and a pregrazing interval proposal are required; alternatively, feeding and grazing restrictions may be proposed. The following additional data are required:

- Data reflecting residues in molasses, refined sugar, and bagasse processed from sugarcane bearing measurable weathered residues. If residues are found to concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.

- Data reflecting residues in or on sugarcane forage at intervals following the last of several (>5) aerial foliar applications of the 5 lb/gal SC/L formulation. Tests must be conducted in FL-(42%), LA(24%) and TX(4%); percent contribution to 1982 sugarcane crop appears in parentheses (Agricultural Statistics, 1983. p. 82. preliminary 1982 figures). The treatment rate in FL and LA must be 0.75 lb ai/A/application and in TX must be 1 lb ai/A/application. A pregrazing interval must be proposed. Alternatively, feeding and grazing restrictions may be proposed.

20/ There are no direct animal treatments for monocrotophos on cattle, goats, hogs, horses, sheep or poultry. Tolerances are being retained for residues of monocrotophos in or on the following raw agricultural commodities which either fed to livestock directly (unprocessed) or processed into commodities which may be fed to livestock: cotton (meal, hulls, soapstock, seed), peanuts (meal, hulls, soapstock), and sugarcane (molasses, bagasse forage). Since additional data are required for the processed products of cottonseed, peanuts,and sugarcane, and additional data or feeding and grazing restrictions are required for sugarcane forage, we are unable to estimate the maximum expected intake of monocrotophos residues by cattle, poultry, or swine at this time. Furthermore, the nature of the residue in animals has not been adequately described. Upon receipt of the requested animal metabolism data, and data pertaining to residues in sugarcane forage and the processed products of cotton, peanuts, and sugarcane, the adequacy of the available data will be assessed and specific data requirements regarding residues in animal products will be determined.

Currently, there are no Canadian or Mexican tolerances for residues of monocrotophos in or on animal products. Codex MRLs have been established for monocrotophos per se in the edible offal and carcase meat of cattle, sheep, goats, and pigs at 0.02 ppm, in poultry and the edible offal of poultry at 0.02 ppm, and in eggs (on a shell-free basis) at 0.02 ppm. The Codex MRLs for monocrotophos per se in milk and milk products are 0.002 and 0.02 ppm, respectively.

21/ Reduction of residue data are required when the assumption of tolerance level residue results in an unsafe level of exposure. Data on the level of residue in food as consumed will be used to obtain a more precise estimate of potential dietary exposure. Any request to reinstate the tomato use must include residue reduction data for raw and processed tomatoes in order to estimate actual dietary exposure from residues of monocrotophos. The data must include residue reductions levels as the raw tomatoes pass through the marketplace and are sold as fresh tomatoes or used in the manufacture of processed tomato products. Also, data on residue reduction levels from processing tomatoes must include data before and after washing, soaking, and canning. Cooking and canning water should also be analyzed. Residue detection levels should reflect those obtainable using GC mass spectometry.

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

§158.125 Residue Chemistry - Continued

22/ A tolerance proposal for the 24(c) use of monocrotophos on Bermuda grass grown for seed is required, if residues of monocrotophos concentrate in processed products from cottonseed, peanuts, or sugarcane appropriate food/feed additive tolerances must be proposed.

23/ The rationale of how the residue data support the proposed tolerance is required to be submitted with any proposed tolerance.

24/ Data are not available to assess the exposure of man to residues of monocrotophos in or on tobacco. The following data are required:

- Data reflecting residues of monocrotophos in or on green, freshly-harvested tobacco following multiple foliar applications of the 3.2 or 5 lb/gal SC/L at 1 lb ai/A; treatments should reflect the use of both ground and aerial equipment. Samples must be harvested 5 days after the last application. If residues are >0.1 ppm, additional data in which pyrolysis products are characterized must be submitted.

25/ Submittal of reference standards are usually required to be submitted for new pesticides and thus are not currently required for monocrotophos.

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission [3]
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A, B	Yes	00115289	No
Photodegradation					
161-2 - In water	TGAI or PAIRA	A, B	Yes	00115290	No
161-3 - On soil	TGAI or PAIRA	A	Yes	00071222	No
161-4 - In Air	TGAI or PAIRA	Not Applicable			
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A, B	Yes	00071223	No
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	-	Yes 27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	Not Applicable			
162-4 - Aerobic Aquatic	TGAI or PAIRA	Not Applicable			
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A, B	Partial	00071228 00071227	Yes[4] 12 Months
163-2 - Volatility (Lab)	TEP	A	No	-	Yes 12 Months
163-3 - Volatility (Field)	TEP	B	No	-	Yes 15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/	
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A, B	No	-	Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	Not Applicable				
164-3 - Forestry	TEP	Not Applicable				
164-4 - Combination and Tank Mixes		Not Applicable			No5/	
164-5 - Soil, Long-term	TEP	A	-	-	No6/	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No	-	Yes7/	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No	-	Yes7/	50 Months
165-3 - Irrigated Crops	TEP	Not Applicable				
165-4 - In Fish	TGAI or PAIRA	A, B	No	-	Yes	12 Months
165-5 - In Aquatic Nontarget Organisms	TEP	Not Applicable				

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

§158.130 Environmental Fate - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Nonfood; C=Aquatic, Food Crop; D=Aquatic, Nonfood; E=Greenhouse, Food Crop; F=Greenhouse, Nonfood; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.

- 12 Month Due Date is September, 1986.
- 15 Month Due Date is December, 1986.
- 27 Month Due Date is December, 1987.
- 39 Month Due Date is December, 1988.
- 50 Month Due Date is November, 1989.

4/ Additional data are needed on the mobility of monocrotophos degradation products in a sandy loam soil.

5/ Data requirements for combination products and tank mixes are not addressed in this standard.

6/ Data are not required since results of a valid aerobic soil metabolism study indicate that 50% of residues dissipate prior to recommended subsequent application.

7/ The Agency is requiring all end-use products registered for outdoor use to bear a restriction on rotating food or feed crops to monocrotophos treated soils unless monocrotophos is registered for use on the rotated crop. This restriction will remain in effect until such time as data are submitted and reviewed which allow the Agency to determine a specific time interval at which rotated crops planted in treated soil will be free of pesticide residues.

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral Toxicity - Rat	TGAI	A, B	Yes	00053705 00005115	No
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A, B	Yes	00099917 00053703 00053704	No
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A, B	No	-	Yes 9 Months
81-7 - Delayed Neurotoxicity - Hen	TGAI	A, B	Yes4/		No4/
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding: - Rodent, and	TGAI	A, B	Yes	00005118 GS0154003	No5/
- Nonrodent (Dog)			Yes6/		No6/
82-2 - 21-Day Dermal - Rabbit	TGAI	A, B	Yes	00005117	No
82-3 - 90-Day Dermal - Rabbit	TGAI	A, B	No		No7/
82-4 - 90-Day Inhalation: - Rat	TGAI	A, B	No		Yes8/ 15 Month
82-5 - 90-Day Neurotoxicity: - Hen	TGAI	A, B	Yes	00087765	No
-Mammal			Yes	00005118 GS0154003	No

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/	
§158.135 Toxicology - Continued						
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species: - Rodent, and	TGAI	A, B	Yes	00005121 00005123 00029424 00046303 GS0154004	No	
- Nonrodent (Dog)			Yes	00005121 00005124 00029425	No	
83-2 - Oncogenicity - 2 species:	TGAI	A, B	Yes			
- Rat (preferred), and				GS0154004	No	
- Mouse (preferred)			No	-	Yes	50 Months
83-3 - Teratogenicity - 2 species:	TGAI	A, B	Yes			
- Rat				GS0154006	No	
- Rabbit			No	-	Yes	15 Months
83-4 - Reproduction - Rat 2-generation	TGAI	A, B	Yes	GS0154005	No	
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A, B	Yes	00114210 GS0154008 GS0154007 GS0154010 GS0154022	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
§158.135 Toxicology - Continued					
84-2 - Structural Chromosomal Aberration	TGAI	A, B	Yes	GS0154009 GS0154008	No
84-4 - Other Genotoxic Effects	TGAI	A, B	Yes	00114210 00043657 00102479 00102476 GS0154022	No
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A, B	No		Yes 24 Months
85-2 - Dermal Penetration	Choice	A, B	No		Yes9/ 12 Months
86-1 - Domestic Animal Safety	Choice	A, B	No		Yes 24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

§158.135 Toxicology - Continued

1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabeled; Choice = Choice of several test substances determined on a case-by-case basis.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.

- 9 Month Due Date is June, 1986.
- 12 Month Due Date is September, 1986.
- 15 Month Due Date is December, 1986.
- 24 Month Due Date is September, 1987.
- 50 Month Due Date is November, 1989.

4/ Satisfied by 90-day neurotoxicity studies.

5/ The following study would be required to support any request to reinstate the use of monocrotophos on tomatoes:

- A 12-week subchronic rat study is required to determine cholinesterase inhibition in plasma, RBC, and brain tissue. This study must include at least 30 animals per dosage level per sex with interim sacrifices at 4 and 8 weeks. The dosage levels must include .03, .06, .09, .15, .50, and .9 parts per million.

6/ Satisfied by the chronic dog studies.

7/ Not required because application of monocrotophos is not expected to involve prolonged exposure to the human skin.

8/ A 21-day inhalation study may be required depending on the residues in tobacco.

9/ In addition to data on dermal penetration, because of the high dermal toxicity of monocrotophos data is required to provide glove permeability information as described in ASTM 739-81-Standard Test Method for Resistance of Protective Materials to Permeation By Hazardous Liquid Chemicals. This data must specify permeability and breakthrough times of materials used in "protective" gloves.

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	A, B	No	-	Yes 27 Months
132-1 - Soil Dissipation	TEP	A, B	No	-	Yes 27 Months
133-3 - Dermal Exposure	TEP	A, B	No	-	Yes 27 Months
133-4 - Inhalation Exposure	TEP	A, B	No	-	Yes 27 Months
§158.142 Spray Drift					
201-1 - Droplet Size Spectrum	TEP	A, B	No	-	Yes 27 Months
201-1 - Drift Field Evaluation	TEP	A, B	No	-	Yes 27 Months

1/ Composition: TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
° 27 Month Due Date is December, 1987.

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Acute Avian Oral Toxicity	TGAI	A, B	Yes	05003191 05000975 GS0154011 GS0154012	No
71-2 - Avian Subacute Dietary Toxicity	TGAI	A, B			
- Upland Game Bird, and			Yes	00022923	No
- Waterfowl			Yes	00022923	No
71-3 - Wild Mammal Toxicity	TGAI	Not Applicable			
71-4 - Avian Reproduction	TGAI				
- Upland Game Bird, and			Partial4/	00086684	No
- Waterfowl			Partial4/	00099121	No
71-5 - Simulated and Actual Field Testing	TEP	A5/	No6/		
- Mammals, and Birds					Yes7/ 24 Months Protocol 4 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
§158.145 Wildlife and Aquatic Organisms - Continued					
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish Toxicity					
- Cold water Fish Species, and	TGAI	A, B	No	-	Yes 9 Months
	TEP	A, B	Yes	GS0154013	No
- Warm water Fish Species	TGAI	A, B	Yes	GS0154014	No
	TEP	A, B	Yes	GS0154014	No
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A, B	Yes	05017538 GS0154014 GS0154015	No
72-3 - Acute Toxicity to Estuarine and Marine Organisms					
- Fish	TGAI	A, B	No	-	Yes8/ 12 Months
- Mollusk	TGAI	A, B	No	-	Yes8/ 12 Months
- Shrimp	TGAI	A, B	No	-	Yes8/ 12 Months
72-4 - Fish Early Life Stage, and Aquatic Invertebrate Life-Cycle	TGAI	A, B	No	-	Reserved9/

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
§158.145 Wildlife and Aquatic Organisms - Continued					
72-5 - Fish - Life-Cycle	TGAI	A, B	No	-	Reserved9/
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product	A, B	No	-	Reserved10/
72-7 - Simulated and Actual Field Testing - Aquatic Organisms	TEP	A, B	No	-	Reserved11/

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

§158.145 Wildlife and Aquatic Organisms - Continued

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood Crop; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.

- 4 Month Due Date is January, 1986.
- 9 Month Due Date is June, 1986.
- 12 Month Due Date is September, 1986.
- 24 Month Due Date is September, 1987.

4/ "Typical" reproductive effects in the field are unlikely from the proposed use of monocrotophos because breeding birds will more likely be exposed to a toxic dose themselves or will lead/feed their brood a toxic dose. Therefore, the avian reproduction tests fulfill the data requirement.

5/ Currently, monocrotophos is used primarily on cotton (38% of annual domestic use) and peanuts (25% of annual domestic use).

6/ Study in wheat (an unregistered crop) does not fulfill the requirement.

7/ Well-designed field testing using Azodrin 5 Water Miscible Insecticide is required in both cotton and peanut growing areas. The field sites should include a number of sites in each growing area. The testing should investigate the two primary routes of exposure, the diet and drinking water and the effects of young fledglings using nest boxes. The design of the field testing protocols, selection of sensitive indicator test species (including avian predators), and the selection of the test sites must be discussed with and reviewed by EPA prior to initiation of the testing; the study protocol must be submitted within 4 months from the date the Standard is issued.

8/ Required for a crop such as cotton where 300,000 acres are grown in coastal counties.

9/ Study may be required pending the receipt of cold water fish LC_{50}, acute data on estuarine and marine organisms and environmental fate data.

10/ Study may be required pending receipt of environmental fate data.

11/ Study may be required pending receipt of acute toxicity data and environmental fate data.

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY	EP		No	-	No3/
NONTARGET AREA PHYTOTOXICITY					
TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI		No	-	No3/
122-1 - Vegetative Vigor	TGAI		No	-	No3/
122-2 - Aquatic Plant Growth	TGAI		No	-	No3/
TIER II					
123-1 - Seed Germination/ Seedling Emergence	TGAI		No	-	No3/
123-1 - Vegetative Vigor	TGAI		No	-	No3/
123-2 - Aquatic Plant Growth	TGAI		No	-	No3/
TIER III					
124-1 - Terrestrial Field	TEP		No	-	No3/
124-2 - Aquatic Field	TEP		No	-	No3/

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. EP = End-use product.

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Nonfood Crop; C=Aquatic, Food Crop; D=Aquatic, Nonfood; E=Greenhouse, Food Crop; F=Greenhouse, Nonfood; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ These requirements are generally waived unless it is believed there is a phytotoxicity problem.

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Data Requirement	Composition 1/	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honeybee acute contact toxicity	TGAI	A, B	Yes	00036935	No
141-2 - Honeybee - toxicity of residues on foliage	TEP	A, B	No	-	Yes4/ 15 Months
141-4 - Honeybee subacute feeding study	(Reserved)5/				
141-5 - Field testing for pollinators	TEP	A, B	No	-	No6/

TABLE A
GENERIC DATA REQUIREMENTS FOR MONOCROTOPHOS

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
§158.155 Nontarget Insect - Continued					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	(Reserved)7/				
142-1 - Aquatic insect life-cycle study	(Reserved)7/				
142-3 - Simulated or actual field testing for aquatic insects	(Reserved)7/				
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved)7/				

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Nonfood; C=Aquatic, Food Crop: D=Aqautic, Nonfood; E=Greenhouse, Food Crop; F=Greenhouse, Nonfood; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
° 15 Month Due Date is December, 1986.
4/ As acute study shows high toxicity to bees, toxicity of residues on foliage must be determined.
5/ Reserved pending development of test methodology.
6/ Requirement for field studies is assessed on a case-by-case basis. Data reviewed to date do not indicate the need for a field study.
7/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL MONOCROTOPHOS

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Timeframe Listed Below 1/
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	R	☒	☐		6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	R	☒	☐		6 Months
61-3 - Discussion of Formation of Impurities	MP	R	☒	☐		6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	CR	☒	☐		12 Months
62-2 - Certification of Limits	MP	R	☒	☐		12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	R	☒	☐		12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	R	☒	☐		6 Months
63-3 - Physical State	MP	R	☒	☐		6 Months
63-4 - Odor	MP	R	☒	☐		6 Months

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TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL MONOCROTOPHOS

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required		Footnote Number	Data Must Be Submitted Within Timeframe Listed Below 1/
			Yes	No		
§158.120 Product Chemistry (Continued) **Physical and Chemical Characteristics (Continued)**						
63-7 - Density, Bulk Density, or Specific Gravity	MP	R	[x]	[ ]		6 Months
63-12 - pH	MP	CR	[x]	[ ]		6 Months
63-14 - Oxidizing or Reducing Action	MP	CR	[x]	[ ]		6 Months
63-15 - Flammability	MP	CR	[x]	[ ]	2	6 Months
63-16 - Explodability	MP	R	[x]	[ ]		6 Months
63-17 - Storage Stability	MP	R	[x]	[ ]		15 Months
63-18 - Viscosity	MP	CR	[x]	[ ]	3	6 Months
63-19 - Miscibility	MP	CR	[x]	[ ]	4	6 Months
63-20 - Corrosion Characteristics	MP	R	[x]	[ ]	5	15 Months
Other Requirements:						
64- 1 - Submittal of samples	MP	CR	[ ]	[x]		

: :

MP = Manufacturing-use Product; R = Required; CR = Conditionally Required

1/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.
- 6 Month Due Date is March, 1986.
- 15 Month Due Date is December, 1986.

2/ This data is required for combustible liquids only.

3/ This data is required for liquids only.

4/ This data is required for emulsifiable liquids only.

5/ This data is required when packaged in metal, plastic or paper containers.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL MONOCROTOPHOS

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? Timeframe for Data Submission 3/
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Acute Oral Toxicity - Rat	MP	Yes	00053705 00005115	No
81-2 - Acute Dermal Toxicity - Rabbit	MP	Yes	00099917 00053703 00053704	No
81-3 - Acute Inhalation Toxicity - Rat	MP	No		Yes 9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	00053704 GS0154002	No
81-5 - Primary Dermal Irritation - Rabbit	MP	Yes	00053705 GS0154001	No
81-6 - Dermal Sensitization - Guinea Pig	MP	No		Yes 9 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING MONOCROTOPHOS

§158.135 Toxicology - Continued

1/ Composition: MP = Manufacturing-use product.

2/ Data must be submitted within the indicated timeframe, based on the date the Guidance Document.

- 6 Month Due Date is March, 1986.
- 12 Month Due Date is September, 1986.
- 15 Month Due Date is December, 1986.

3/ Since the only MUP currently registered is also the technical (EPA Reg. No. 201-219), the same studies satisfy both requirements.

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA sec. 3(c)(2)(B). The tables following Chapter I list the data required for maintaining the registrability of each product.

EPA has determined that additional generic data described in Table A must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA sec. 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data[1] Must be Submitted. You may determine which generic data you must submit by consulting Table A following Chapter I. That table lists the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required studies must be conducted in accordance with EPA approved protocols (such as those contained in the Pesticide Assessment Guidelines [2] or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you do not wish to develop data in support of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

For certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: "Typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter III of this document.

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[1] Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient, regardless of the product's unique composition or specific use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

[2] The Pesticide Assessment Guidelines are available in hard copy or microfiche from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-3] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

(b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Pesticide Assessment Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

OR

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

OR

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-4)*/

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*/ FIFRA sec. 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued on next page)

OR

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

OR

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager.

(Footnote continued from previous page)
In EPA's opinion, joint data development by all registrants subject to a data requirement or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it should encourage joint testing rather than duplicative testing, and that suspension should be withheld in certain cases to further this goal. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration.

The extension request should state the reasons why you believe that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: Unless stated otherwise in Section I, Regulatory Position and Rationale, this Section applies only to manufacturing use products, not to end use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill gaps identified by EPA concerning your product. Under the authority of FIFRA sec. 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

Table B--Product-Specific Data Requirements for Manufacturing Use Products--lists the product specific data you must submit. Data that are required to be submitted are identified in the column of those tables entitled "Must Data By Submitted Under §3(c)(2)(B)."

IV. SUBMISSION OF REVISED LABELING

Note: This section applies to end use products only to the extent described in Section I (Regulatory Position and Rationale). Otherwise, the following information pertains exclusively to manufacturing use products.

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients. Labeling requirements are set out in 40 CFR 162.10 (see Appendix IV-1) and are summarized for products containing this active ingredient as part of this Guidance Document (See Appendix IV-2). Applications submitted in response to this notice must include draft labeling for Agency review.

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*/ Product specific data pertain to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicity data.

If you fail to submit revised labeling information complying with this section (supplemented by requirements described in Section I, Regulatory Position and Rationale), EPA may issue a notice of intent to cancel the registration under FIFRA sec. 6(b)(1).

A. Label Contents

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Appendix IV-2.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. See Appendix IV-1. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR 162.10 (h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR 162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C).

c. A "non-flammable aerosol" is one which meets the following criteria:

i. The flame extension is zero inches;

ii. There is no flashback; and

iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label. It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section I indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If Section I of this Guidance Document indicates that your product has been classified for restricted use, the following label requirements apply:

1. Front panel statement of restricted use classification.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

   a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

   b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

   c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B [There is no Item 9B].

Item 9C. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B [There is no Item 10B].

Item 10C. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-4 to determine the disposal instructions appropriate for your products.

Item 10D. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR 162.10]

B. Collateral Labeling

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

A. For Manufacturing Products (MP) containing monocrotophos as an active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division at the address given at the end of this section the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit to the Product Manager on the Registration Division:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data.

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99 for latest requirements.

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

B. For Manufacturing Use Products containing monocrotophos in combination with other active ingredients

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the agreed schedule cannot be met, notify the Product Manager and the Office of Compliance Monitoring.

C. For End Use Products containing monocrotophos alone or in combination with other active ingredients:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet," EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

If on the Summary Sheet, you commit to develop the data, request a minor chemical exemption, present arguments that a data requirement is not applicable, or submit protocols or modified protocols for Agency review, you must also submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This information should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted.)

2. Within 6 months from receipt of this document you must submit:

a. Confidential Statement of Formula, EPA Form 8570-4.

b. Product-Specific Data Report, EPA Form 8580-4 (Appendix III-1).

c. Two copies of any required product-specific data. (Refer to Table C).

d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section I (Regulatory Position and Rationale) of this guidance document. Labeling should be either typewritten text on 8 1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8 1/2 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99 for latest requirements.

3. Within the time frames set forth in Table A, submit all generic data, unless you are eligible for the formulator's exemption.

D. For intrastate products containing monocrotophos either as the sole active ingredient or in combination with other active ingredients

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Applications and other required information should be submitted to the following address:

William H. Miller
Product Manager, Team 16
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460
Phone No. (703) 557-2600

The address for submission to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW.
Washington, D.C. 20460

Appendix II-1

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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00005117	Doyle, R.L.; Elsea, J.R. (1965) Repeated Application of Technical Bidrin Insecticide and Azodrin to the Skin of Rabbits: P-44. (Unpublished study received April 2, 1970, under 0F0861; prepared by Hill Top Research, Inc., submitted by Shell Chemical, Co., Washington, DC; CDL:091487-J)
00005118	Shellenberger, T.E.; Newell, G.W. (1964) Technical Report--Part I: Subacute Toxicity and Cholinesterase Study of Shell Compound SD 9129--Rat and Dog: SRI Project B-4843. (Unpublished study including addendum, received April 2, 1970, under 0F0861; prepared by Stanford Research Institute, submitted by Shell Chemical Co., Washington, DC; CDL:091487-M)
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Appendix II-3

OMB Approval No. 2000-0468 (Expires [illegible])

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO

PRODUCT NAME

APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

Appendix II-4

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

qualify, certify ALL four items)

I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

his firm or group of firms is referred to below as "my firm".)

My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was maoc to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

lowever, none of those firm(s) accepted my offer.

. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) abov have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inforr me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statemen does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

YPED NAME	SIGNATURE	DATE

PRODUCT SPECIFIC DATA REPORT

EPA Registration No.________________ Guidance Document for____________________

Date____________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

~~cant obtained the data from another firm (identify), applicant copied data from a publication, applicant obtained a copy of the data from EPA).~~

~~(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:~~

~~(1) The data the applicant has submitted to EPA under paragraph (b) of this section;~~

~~(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and~~

~~(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.~~

~~(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:~~

~~(1) A notification of the applicant's intent to apply for registration, including the proposed product name;~~

~~(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);~~

~~(3) An identification of the item(s) of data to which the offer applies;~~

~~(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and~~

~~(5) The applicant's name, address, and telephone number.~~

~~(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:~~

~~(1) All data submitted or specifically cited by the applicant in support of the registration; and~~

~~(2) Each other item of data in the Agency's files which:~~

~~(i) Concerns the properties or effects of any such active ingredient; and~~

~~(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.~~

(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)

[44 FR 27932, May 11, 1979]

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD₅₀	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC₅₀	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD₅₀	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practi

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cal treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of

100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) Pressurized Containers	
Flash point at or below 20° F; if there is a flashback at any valve opening	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) Nonpressurized Containers	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

~~§ 162.11 Criteria for determinations of unreasonable adverse effects.~~

~~(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing*—(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five (45) days from the date such notice is sent to submit evidence in rebuttal of the presumption; provided, however, that for good cause shown the Administrator may grant an additional sixty~~

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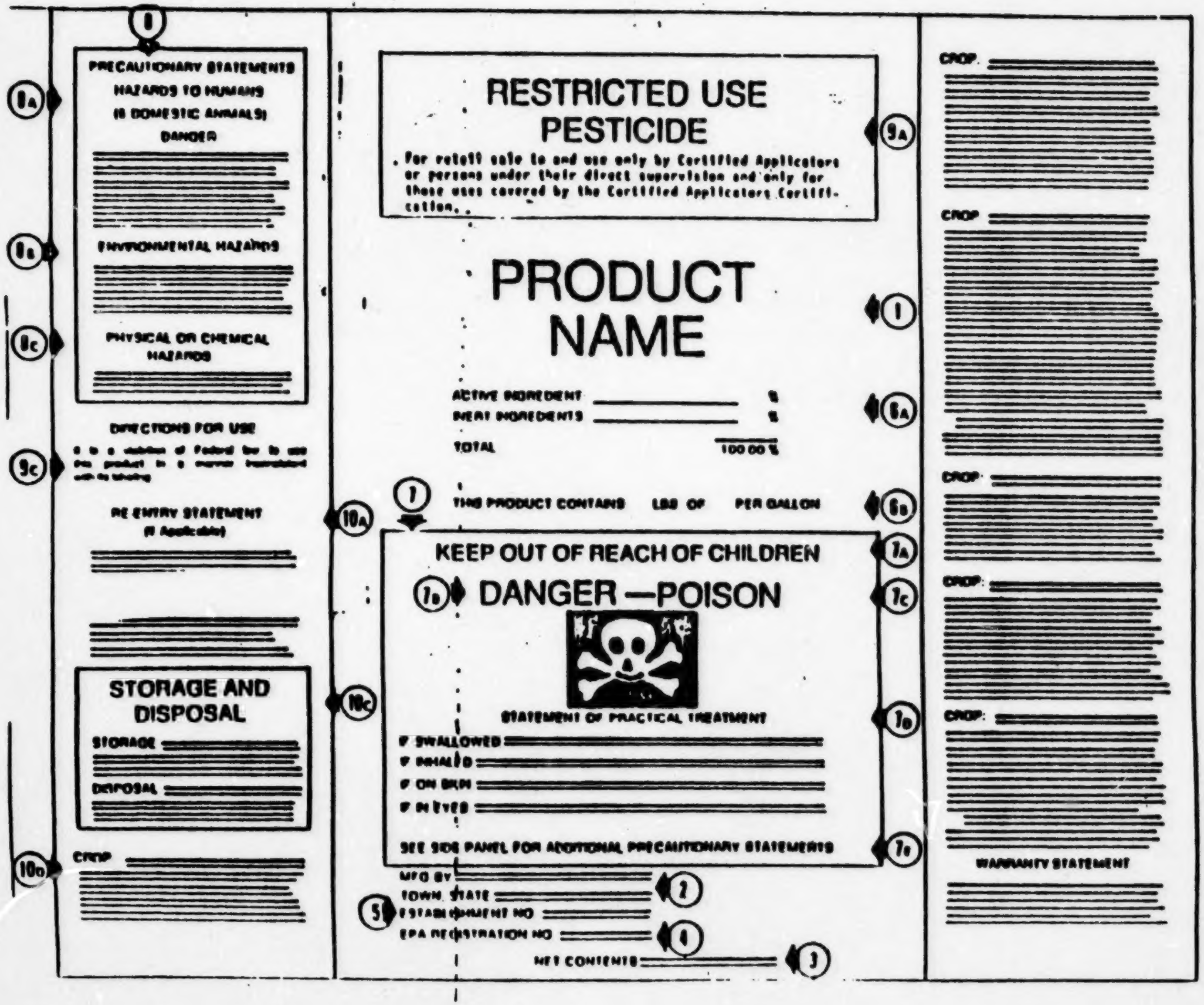
8
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER
8A
ENVIRONMENTAL HAZARDS
8B
PHYSICAL OR CHEMICAL
HAZARDS
8C
DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling
9C
RE-ENTRY STATEMENT
(If Applicable)
STORAGE AND
DISPOSAL
STORAGE
DISPOSAL
10A
10C
CROP
10D
RESTRICTED USE
PESTICIDE
For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicators Certification.
9A
PRODUCT
NAME
1
ACTIVE INGREDIENT
INERT INGREDIENTS
%
%
TOTAL
100.00 %
6A
7
THIS PRODUCT CONTAINS
LBS OF
PER GALLON
6B
KEEP OUT OF REACH OF CHILDREN
7A
7B
DANGER —POISON
7C
STATEMENT OF PRACTICAL TREATMENT
7D
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
7E
MFD BY
TOWN, STATE
2
5
ESTABLISHMENT NO
EPA REGISTRATION NO
4
NET CONTENTS
3
CROP:
CROP:
CROP:
CROP:
CROP:
WARRANTY STATEMENT

APPENDIX IV-2

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following heading of directions for use		
10A	Reentry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D	Directions for use	All products	None	None	May be in metric as well as U.S. units

Appendix IV-3

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

Appendix IV-4

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	6 point
Above 10 to 15	8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List) Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
    (disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
    (kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)

Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

Appendix IV-4
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide

Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®
Vinyl chloride
Xylene